

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars:

1. Amendments and Support for Same

By the Response, claims 1 and 2 have been amended to more particularly point out and distinctly claim the subject matter of the invention. Support for the amended features can be found in, e.g., Embodiment 1 described in the original specification. No new matter has been added. Accordingly, claims 1-10 are respectfully submitted for consideration. Approval and entry of the amendments are respectfully requested.

2. Claim rejections under 35 U.S.C. §112, 2nd paragraph

With respect to the rejection of claim 10 under 35 U.S.C. §112, 2nd paragraph, Applicant has corrected the dependency of claim 10 from claim 1 to claim 3, and, thus, provided proper antecedent basis for “the guiding member.” In view of the amendments and arguments set forth above, Applicant respectfully requests reconsideration and withdrawal of the §112, 2nd paragraph, rejections of claim 10.

3. Rejection under 35 U.S.C. §102(b)

With respect to the rejection of claims 1-7 under 35 U.S.C. §102(b) as being anticipated by Fukuda (US 3,871,358), Applicant respectfully traverses the rejection at least for the reason that Fukuda fails describe each and every limitation recited in the rejected claims.

The present invention guides a medical instrument into a digestive organ from an oral cavity through a pharynx. In this case, one of the problems is that there exist strong muscles around the pharynx of a human being. These strong muscles automatically contract to close the pharynx upon sensing a foreign object. To overcome this automatic reflex, the tubular member of the present invention has a larger diameter than that of the pharynx to allow the

expansion of the pharynx so that the medical instrument can be easily inserted into the digestive organ.

As amended, independent claims 1 and 2 further recite the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx. By using a tubular member that is formed in a curve shape in advance to conform to the shape of the pharynx, low-impact expansion of the pharynx where strong muscles exist can be accomplished.

In contrast, Fukuda generally describes a tube member that is inserted from an anus into a bowel to guide an endoscope into the bowel. Further, the tube member of Fukuda is a straight-pipe shape before application, and is curved only by inserting into the bowel. Applicant respectfully notes that the tube member of Fukuda is not retained in a pharynx as in the presently claimed invention, and the tube member of Fukuda is used in a different region of a body than that of the present invention.

At least for the reasons set forth above, Applicant respectfully asserts that Fukuda does not teach, disclose, or suggest the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx, as recited in Applicant's amended claims.

Applicant's claimed invention as recited in amended claim 2 further distinguishes over Fukuda. As amended, claim 2 recites a guiding member and inserting a guiding member with a smaller diameter than the tubular member into the pharynx earlier than (i.e., prior to) inserting the tubular member. By such a configuration of a guiding member and its insertion, the pharynx is allowed to expand gradually and with less impact. On the other hand, the endoscope of Fukuda is guided by the tubular member inserted earlier, and there is no guide for the tube member.

Consequently, since each and every feature of the present claims is not taught (and is not inherent) in Fukuda, as is required by MPEP Chapter 2131 in order to establish

anticipation, the rejection of claims 1-7, under 35 U.S.C. §102(b), as anticipated by Fukuda is improper.

In view of the amendment and arguments set forth above, Applicant respectfully requests the Examiner to consider Fukuda in its entirety as set forth in MPEP 2141.02(VI). Further, Applicant respectfully requests reconsideration and withdrawal of the §102(b) rejection of claims 1-7.

4. Rejections under 35 U.S.C. §103(a)

With respect to the rejection of claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over Fukuda in view of Turnbull (US 5,996,582), and to the rejection of claim 9 under 35 U.S.C. §103(a) as being unpatentable over Fukuda in view of Gomez (US 6,053,166), Applicant respectfully traverses the rejection at least for the reason set forth above in relation to the rejection of independent claims 1 and 2 over Fukuda, and for the reason that Fukuda, Turnbull, and Gomez, combined or separately, fail to teach, disclose, or suggest all of the limitation recited in the rejected claims.

Turnbull and Gomez generally describe an assembly inserted into a trachea, which is unrelated to Applicant's claimed invention. Moreover, Turnbull and Gomez fail to teach, disclose, or suggest at least the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx, as recited in amended claims 1 and 2.

Further, Turnbull and Gomez fail to teach, disclose, or suggest recites a guide member and inserting the guiding member with a smaller diameter than the tubular member into the pharynx earlier than (i.e., prior to) inserting the tubular member, as recited in amended claim 2.

The requirements for establishing a *prima facie* case of obviousness, as detailed in MPEP § 2143 - 2143.03 (pages 2100-122 - 2100-136), are: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to combine the teachings;

second, there must be a reasonable expectation of success; and, finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

Further, according to MPEP §2141(I), Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Moreover, according to MPEP §2141(II), when applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

As Turnbull, Gomez, and Fukuda, combined or separately, fail to teach, disclose, or suggest each and every feature of claims 1-4 and 9, the obviousness rejections are improper.

In view of the amendment and arguments set forth above, Applicant respectfully requests the Examiner to follow tenets A-D in rejecting claims 1-4 and 9. Further, Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection of claims 1-4 and 9.

5. Conclusion

In view of the amendments to the claims, and in further view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is requested that claims 1-10 be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the Applicant's representative, the Examiner is invited to contact the undersigned at the numbers shown.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

/Donald R. Studebaker/
Donald R. Studebaker
Registration No. 32,815

Studebaker & Brackett PC
1890 Preston White Drive
Suite 105
Reston, Virginia 20191
(703) 390-9051
Fax: (703) 390-1277
don.studebaker@sbpatentlaw.com